New Jersey Dept. of Health and Senior Services

H1N1 Vaccination Program FAQs
PROVIDER SITE

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GLOSSARY OF TERMS

H1N1 Vaccine System: NJDHSS's H1N1 vaccine data tracking system which resides in and uses the format of the New Jersey Immunization Information System (NJIIS), the state's immunization registry.

Provider: any entity that will receive vaccine and/or administer vaccinations; providers include hospitals, FQHCs, local health departments, LINCS agencies, pharmacies, pharmacists, physicians, and employee health services.

Provider site: physical location where vaccine will be received and/or administered.

Provider type: individual authorized to bind a provider site to receive vaccines and/or administer vaccinations; provider types can only be licensed physicians, advanced practice nurses, pharmacies, and pharmacists.

User: any authorized individual associated with a provider site who will or has access to the H1N1 Vaccine System in order to administer vaccine-related information (e.g., doses-administered reports, vaccine inventory data); examples of users include physician office managers, data entry clerks, and health care professionals.

BECOMING A PROVIDER

1. **How does a New Jersey provider site register to receive the H1N1 vaccine?**

   It is required that **all** providers interested in receiving a direct shipment or being a "vaccinator only" site must register online at the H1N1 Vaccine System at http://nj.gov/health/flu/h1n1.shtml. Once there, look to the left side of the webpage and click on "H1N1 Vaccine Provider Agreement."

2. **Can I fax or send a paper copy to register?**

   No. Paper copies will not be accepted. Providers must register electronically online at http://nj.gov/health/flu/h1n1.shtml. Once there, look to the left side of the webpage and click on "H1N1 Vaccine Provider Agreement."

3. Must I have a valid email address?

Yes, an email address must be provided in order to receive a confirmation of your enrollment and the status of your enrollment application. There will be information in the email that you will need to receive Webinar training on the H1N1 Vaccine System for use during the H1N1 influenza season.

4. Will I get an account number or provider identification number (PIN)?

Yes, once a provider is registered, he or she will be assigned a PIN that will be needed to electronically order vaccine, electronically record the vaccines that you administer and electronically record the temperatures of the refrigerator in which the H1N1 vaccine is stored.

5. How do commercial facilities or providers request vaccines?

Any facility interested in receiving the H1N1 vaccine must register as a provider. (Refer to question #1 for the enrollment website.)

6. Do individual provider sites need to register if they are not a "ship-to" site but will be receiving vaccine from a parent company?

Yes, all provider sites, whether direct "ship-to" or "vaccination only" site, must register to receive the vaccines. That is one of the ways that the State will be able to monitor the vaccine administered and transferred from one location to another. Individual staff within those sites do not need to register. Only one individual at the site is required to register in order to serve as the point of contact for the NJDHSS and LHD. If you have further questions regarding this, your parent company should contact the NJ Immunization Program at 609-588-7512 for more guidance.

7. I am with a local health department or LINCS agency. Who is eligible to complete and sign the Provider Agreement?

To be eligible to complete and sign the Provider Agreement, an individual must have a current license as a D.O., M.D., Advanced Practice Nurse, Pharmacist, or Pharmacy in order to legally bind the terms of the Provider Agreement. In the H1N1 Vaccine System, this individual is identified in the "Provider Type" section.

A registered site can designate up to three individuals who will have the ability to order vaccine. An indefinite number of individuals can serve as data entry personnel, responsible for entering data on the doses of vaccine administered.

Criteria for Approving Submitted Application as H1N1 Sites

Combination Ship-to & Vaccinator Site:

- **Provider must be licensed or certified to vaccinate in New Jersey.**
- **Provider address must be a business not a home address or PO Box.**
- **Telephone number must be an office number not a cell or mobile #.**
- **Must have internet access.**
- **Provider must have a computer or laptop from which to order vaccine, record vaccine accountability and refrigerator temperatures where the H1N1 vaccine is stored.**
- **Each person that will administer vaccine must register as a user of the H1N1 Vaccine System.**
- **Refrigerator must be a single-door household size (13 cu. ft) or larger no dorm-style or bar-style refrigerators permitted.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**

Ship-to only Site:

- **Refrigerator must be a single-door household size (13 cu. ft) or larger.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**
- **Must have internet access.**
- **Provider must have a computer or laptop from which to order vaccine, record vaccine inventory and refrigerator temperatures where the H1N1 vaccine is stored.**
- **Provider address must be a business not a home address or PO Box suitable to accept delivery of large shipments of vaccine for distribution to vaccinator-only sites.**
- **Telephone number must be an office number not a cell or mobile #.**

Vaccinator –Only Site

- **Provider must be licensed or certified to vaccinate in New Jersey.**
- **Provider address must be a business not a home address or PO Box.**
- **Telephone number must be an office number not a cell or mobile #.**
- **Must have internet access.**
- **Provide must have a computer or laptop from which to order vaccine, record**

vaccine accountability and refrigerator temperatures where the H1N1 vaccine is stored.

- **Each person that will administer vaccine must register as a user on H1N1 Vaccine System.**
- **Refrigerator must be a single-door household size (13 cu. ft) or larger, no dorm-style or bar-style refrigerators permitted.**
- **Refrigerator must maintain a consistent temperature between 35 degrees – 46 degrees.**
- **Thermometer to record temperatures should be housed in the unit in which the H1N1 vaccine will be stored.**

New Jersey Department of Health and Senior Services (NJDHSS)
H1N1 Vaccine System Provider Registration in Brief: Health Care Providers

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for health care providers (e.g., physicians, pharmacists, advanced practice nurses).

Step 1 – Provider Site Registration

Providers need to register their office or facility as a site for administering H1N1 vaccines. Eligible providers include physicians, pharmacies, hospitals, employee health programs, local health departments and federally qualified health centers. If you have more than one office/location, you will need to register each location separately. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

Once you register in the H1N1 Vaccine System, your information will be approved by the appropriate LINCS agency and/or local health department. Once approved and then verified by NJDHSS, you will receive an email with your PIN and a security access code. If you enroll during September 17 to 25, 2009, you should receive your PIN and security access code no later than the first week of October 2009. If you are not approved, you will receive an email notification, and you can contact the LINCS agency in your jurisdiction to get further information.

You can be approved as a *ship-to site*, where the vaccine will be delivered to your location, or as a *vaccinator only site*, where you will need to pick up the vaccine from a designated site in your jurisdiction such as a local health department or LINCS agency.

Important –

- Please provide a valid email address in the provider registration process as all communication is via email.

- Current New Jersey Immunization Information System (NJIIS) providers need to register for participation in the H1N1 Vaccine System.

Step 2 – User Registration

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. All users will have the ability to track H1N1 vaccine inventory, complete temperature logs, and update administered doses for each person you vaccinate. In addition, ship-to site users will have the ability to order vaccine online through the H1N1 Vaccine System.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self-training through a user manual. Attending the one-hour webinar is highly encouraged as it includes a Q &A session. Training sessions are scheduled from September 28 to October 9, 2009.

Step 3 – Vaccine Order (Only for Ship-to Sites)

After completing the previous two steps, i.e., registering your facility and creating your user account, as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification), you can start ordering H1N1 vaccines by clicking on the "Order Vaccine" tab. Vaccine ordering privileges will be restricted to three users per registered ship-to site. As mentioned above, training is available to help you with your ordering process.

Note: vaccinator only sites will have to place their vaccine orders through the designated ship-to sites in their jurisdiction such as the LINCS agency or local health department.

Step 4 – Record Patient Vaccination

Use your user name and password (created in Step 2) to access data entry screens for reporting patient information. If the patient already exists in NJIIS, the state's immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient's name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the doses already shipped to you. Any registered user from your facility can enter patient vaccination information.

Current NJIIS users will also be able to document H1N1 vaccines through NJIIS screens.

New Jersey Department of Health and Senior Services (NJDHSS)
H1N1 Vaccine System Provider Registration in Brief:
LINCS Agencies and Local Health Departments (LHDs)

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for LINCS agencies and LHDs.

Step 1 – Provider Registration and Approval

All LINCS agencies and local health departments need to register in the H1N1 Vaccine System if they want to be provider sites for administering H1N1 vaccines. You will receive your approval email from NJDHSS after registration in the H1N1 Vaccine System. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

In addition, two LINCS agency staff will be assigned H1N1 Vaccine System administrative privileges to "approve" ship-to or vaccinator only sites within their jurisdiction ("LINCS H1N1 Vaccine System administrators"). One person per local health department will be assigned H1N1 Vaccine System privileges to view the list of providers enrolling in their county in order to help the LINCS agencies in the approval process. Ship-to sites will receive vaccine shipments at the address indicated in their registration information, while vaccinator only sites will be asked to pick up their vaccine orders from a designated site such as the LINCS agency or local health department. As you have a limited number of ship-to sites in your jurisdiction, please use your judgment in allocating them; NJDHSS has provided some guidance for your consideration as you review provider registration information.

Providers will be able to register in the H1N1 Vaccine System during September 17 to 25, 2009. As the LINCS agency, you are requested to work with local health departments in your jurisdiction and to approve providers as *ship-to sites*, where vaccine will be delivered to these locations, or as *vaccinator only sites*, where these sites will need to pick up vaccines from a designated ship-to site such as the local health department or LINCS agency. You will need to check off a flag on the H1N1 Vaccine System approval screen to designate ship-to sites. You will be able to start approving providers starting Wednesday September 23, 2009, and should finalize your approvals no later than October 2, 2009.

Once you approve a site, NJDHSS will verify eligibility and send out an email to the approved providers with their PIN, security access code and training information.

Providers that are not LINCS-approved will be sent an email informing them that their applications have not been approved and that they can contact the designated LINCS H1N1 Vaccine System administrators for further information. The email address of the LINCS H1N1 Vaccine administrators will be included in the email.

Step 2 – User Registration

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. Users will have the ability to order vaccine, track vaccine inventory, complete temperature logs, and update administered doses by inputting the information for each person you vaccinate.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self training through a user manual. Attending the one-hour webinar is highly encouraged as it includes a Q &A session. Training sessions to help you through the approval process will be provided on September 24 and 25, 2009, through the New Jersey Learning Management Network (NJLMN).

Step 3 – Vaccine Order

After completing the previous steps, i.e., registering your facility, creating your user ID, and attending the training, you can start ordering the H1N1 vaccines by clicking on the "Order Vaccine" tab as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification). As a LINCS agency or LHD, you can also order vaccine for other vaccinator only sites. Only three users per registered facility can be assigned vaccine ordering privileges.

Step 4 – Record Patient Vaccination

Use your user name and password to access data entry screens for reporting patient vaccination information. If the patient already exists in the New Jersey Immunization Information System, the state's immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient's name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the ones already shipped to you. Any registered user in your organization can enter patient vaccination information.

New Jersey Department of Health and Senior Services (NJDHSS)
H1N1 Vaccine System Provider Registration in Brief:
Hospitals and Federally Qualified Health Centers (FQHCs)

The following information briefly outlines the NJDHSS H1N1 Vaccine System registration processes for hospitals and FQHCs.

Step 1 – Provider Site Registration

Hospitals and FQHCs need to register in the H1N1 Vaccine System if they want to be provider sites for administering H1N1 vaccines. If you have more than one location, you will need to register each location separately. In order to register as a provider site, you will need to provide a valid license number for one of the following license types – medical doctor, doctor of osteopathy, advanced practice nurse, pharmacist or pharmacy.

Once you register in the H1N1 Vaccine System, your information will be approved and verified by NJDHSS. Once approved and verified, you will receive an email with your PIN and a security access code. If you enroll during September 17 to 25, 2009, you should receive your PIN and security access code no later than the first week of October 2009.

Important –

- Please provide a valid email address in the provider registration process as all communication is via email.
- Current New Jersey Immunization Information System (NJIIS) providers need to register for participation in the H1N1 Vaccine System.

Step 2 – User Registration

After you receive your PIN and security access code, you can enroll yourself and additional members of your staff as users of the H1N1 Vaccine System. All users will have the ability to track H1N1 vaccine inventory, complete temperature logs, and update administered doses for each person you vaccinate. In addition, you will have the ability to order vaccine online through the H1N1 Vaccine System.

The email with your PIN and security access code will also include information on online training available through a webinar and/or self-training through a user manual. Attending the one-hour webinar is highly encouraged as it includes a Q &A session. Training to help you through the approval process will be provided on September 24 and 25, 2009, through the New Jersey Learning Management Network (NJLMN). If you are unable to make these early sessions (which target hospitals, FQHCs, LINCS agencies and local health departments), you can attend additional training sessions available to general health care providers, scheduled from September 28 to October 9, 2009.

Step 3 – Vaccine Order

After completing the previous two steps, i.e., registering your facility and creating your user account, as soon as NJDHSS is given permission to submit orders (NJDHSS will send out a notification), you can start ordering H1N1 vaccines by clicking on the "Order Vaccine" tab. Vaccine ordering privileges will be restricted to three users per registered site. As mentioned above, training is available to help you with your ordering process.

Step 4 – Record Patient Vaccination

Use your user name and password (created in Step 2) to access data entry screens for reporting patient information. If the patient already exists in NJIIS, the state's immunization registry, you will only need to update the H1N1 dose; otherwise you will enter the patient's name, address and date of birth to complete the record. You will not be able to order additional vaccine doses if you do not account for the doses already shipped to you. Any registered user from your facility can enter patient vaccination information.

Current NJIIS users will also be able to document H1N1 vaccines through NJIIS screens.

REPORTING

8. Are providers required to report each dose administered to an individual?

Yes, all doses administered must be reported to the New Jersey Department of Health and Senior Services electronically at http://nj.gov/health/flu/h1n1.shtml .

9. How do I inform the New Jersey Department of Health and Senior Services of the doses used or administered?

All enrolled providers will be sent by email the information needed to access a Webinar training on the H1N1 Vaccine System. The 20-minute training will show where all doses administered must be electronically entered and reported in the H1N1 Vaccine System.

10. **Is there a way to transfer data to the registry from other electronic systems?**
Yes, the H1N1 Vaccine System is capable of receiving data from various electronic systems. The documentation is available on the NJ Immunization Information System (NJIIS), the state's immunization registry, website at

http://nj.gov/health/flu/h1n1.shtml. Data must include the lot number of the vaccine administered to an individual. This is a CDC requirement. The H1N1 Vaccine System also allows documenting refrigerator temperature logs, and the doses administered.

LOGISTICS

11. How will the public be able to locate a vaccination location?

It is anticipated that there will be multiple sites to which the public can go to be vaccinated. They should contact the Local Health Department for locations that are available for vaccination in their area or go to the NJDHSS website at http://nj.gov/health/flu/findflushot.shtml or at the Maxim website at http://www.FindaFluShot.com for vaccination locations.

RECEIVING SITES

12. **What kind of providers can be designated as "vaccinator only" site?**
Providers that have the capability to receive, store and administer vaccine, including but not limited to provider offices, occupational health clinics, hospitals, local health departments, community vaccinators and pharmacies.

13. **How many sites can be designated to be a "ship-to" site?**
There will be a maximum of approximately 90,000 sites to which vaccine can be shipped via centralized distribution. CDC has developed a formula to determine the maximum number of sites within each state. New Jersey has 2,353 "ship-to" sites. More information is available on the CDC website.

14. **What is the difference between direct "ship-to" and "vaccinator site"?**

Direct "ship-to" sites are designated sites to receive the shipment of vaccine from McKesson while "vaccinator sites" will vaccinate only, but not receive the vaccine directly from McKesson. "Vaccintor only" sites need to contact their local LINCS agency to obtain the vaccine.

14. How many direct "ship-to" sites are in New Jersey?

New Jersey has 2,353 direct "ship-to" sites.

SHIPMENTS/RECEIVING SITES/LOGISTICS

15. How will vaccine be shipped to New Jersey?

Vaccine will be shipped by CDC's contractor for centralized distribution, McKesson Specialty, to hospitals, clinics, doctors' offices, health departments, and other providers of vaccines that have been designated as "ship-to" sites.

16. How frequently will vaccine shipments arrive to New Jersey ship-to sites?

As details of distribution are finalized, CDC will communicate with states about the anticipated time period between placing vaccine orders and receiving shipments.

17. How many sites can be designated as "vaccinator only" sites?

One of the key benefits of using a centralized, third party distributor to support H1N1 vaccine distribution is that it allows distribution of doses to a much larger number of providers sites than would be feasible with direct manufacturer distribution. Thus, we will be able to serve a significantly larger provider base than the original state "ship-to" sites, and are planning to be able to accommodate more providers than are currently served by the VFC program.

18. How long will it take for vaccine to arrive once I place my order?

The shipping timelines for 2009 H1N1 vaccine are currently being established between CDC and McKesson. Information will be provided to state planners as soon as it is available.

19. What should states expect with respect to frequency of vaccine shipments?

Vaccine will be shipped as it becomes available, taking into account state allocations and orders. The process will be modeled after that utilized by immunization programs that order seasonal influenza vaccine off the federal contract, except for the shipment timeline, which is not yet finalized.

20. Can a "ship-to" site transfer vaccine to another "ship-to" or "vaccinator site"?

Yes, as long as the site to which the vaccine is being transferred and the site receiving the vaccine are registered as H1N1 vaccine sites.

21. Can a "ship-to" or vaccinator site transfer vaccine to another location?

Yes, if properly packaged for transport with a thermometer inside to monitor the container temperature in which the vaccine is being moved. Maintaining the cold-chain is very important to protecting the potency of the vaccine.

22. What is the minimum dose order for shipments of 2009 H1N1 vaccine?

For each vaccine formulation (identified by its National Drug Code) the minimum

dose order is 100 doses and all orders must be placed in increments of 100 doses. Each ancillary supply kit will contain supplies to support 100 doses of vaccine, with different kits available for prefilled syringe products and for multi-dose vial products.

23. When will vaccine shipping begin?

Planners should assume shipping of vaccine will begin mid-October, although there is a possibility that some vaccine may be available for shipping starting in late September. Visit the CDC website for the latest information on vaccine availability.

PRIORITY GROUPS

24. Who can be vaccinated first with the initial supply of H1N1 vaccine that comes to New Jersey?

The Advisory Committee on Immunization Practices (ACIP) has established a priority listing for vaccination with H1N1 vaccine. Based on what is known now, it seems likely recommendations will include that, pregnant women, younger people (6 months – 24 years of age), household contacts of children less than 6 months of age, healthcare workers (HCW), and people aged 25 years – 64 years who have underlying health conditions seek vaccination as soon as a vaccine is available.

ACIP - a panel made up of medical and public health experts, met July 29, 2009, to make recommendations on who should receive the new H1N1 vaccines when it becomes available. While some issues are still unknown, such as how severe the flu season will be, the ACIP considered several factors, including current disease patterns, populations most at risk for severe illness based on current trends in illness, hospitalizations and deaths, how much vaccine is expected to be available, and the timing of vaccine availability.

The groups recommended to receive the 2009 H1N1 influenza vaccine include:

Pregnant women because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;

Household contacts and caregivers for children younger than 6 months of age because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants younger than 6 months old might help protect infants by "cocooning" them from the virus.

Healthcare and emergency medical services personnel because infections among healthcare workers have been reported and this can be a potential source of infection for

vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity.

All people from 6 months through 24 years of age

Children from 6 months through 18 years of age because cases of 2009 H1N1 influenza have been seen in children who are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and

Young adults 19 through 24 years of age because many cases of 2009 H1N1 influenza have been seen in these healthy young adults and they often live, work and study in close proximity, and they are a frequently mobile population; and,

Persons aged 25 through 64 years of age who have health conditions associated with higher risk of medical complications from influenza.

25. What are the underlying health conditions?

Currently, insufficient data are available to determine who is at higher risk for complications of novel influenza A (H1N1) virus infections. Thus, at this time, the same age and risk groups who are at higher risk for seasonal influenza complications should also be considered at higher risk for swine-origin influenza complications.

Groups at higher risk for seasonal influenza complications include:

- Children less than 5 years old;
- Persons aged 65 years or older;
- Children and adolescents (less than 18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- Pregnant women;
- Adults and children who have chronic pulmonary, cardiovascular, hepatic, hematological, neurologic, neuromuscular, or metabolic disorders;

- Residents of nursing homes and other chronic-care facilities.

26. How will the state determine that vaccine is given to the recommended target groups?

Each provider that enrolls to be a "ship-to" or "vaccination only" site will sign the Provider Agreement in which they will agree to comply with the ACIP recommendations for the H1N1 vaccine.

27. **Given the potential for large amounts of vaccine available during the first month of vaccine shipments, are priority groups needed?**

It is not expected that there will be a shortage of the H1N1 vaccine, but availability and demand can be unpredictable. There is some possibility that initially the vaccine will be available in limited quantities, and priority groups may be needed.

28. **Will there be requirements regarding documentation of priority group membership?**

There will be no federal requirements or New Jersey requirements for vaccinators to require documentation of priority group status such as a doctor's note documenting pregnancy or risk status.

29. How will the State determine that the vaccine can be administered to other target populations?

Once the demand for vaccine for the prioritized groups has been met at the local level, providers should also begin vaccinating everyone from the ages of 25 through 64 years. Current studies indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, providers should offer vaccination to people 65 or older.

30. Are school nurses considered to be health care workers (HCW)?

Yes, school nurses are considered to be HCWs. School nurses provide direct medical care to students, including those who might have respiratory illness.

VACCINE AND SUPPLIES

31. **Will vaccine be in multi-dose vials?**
    The majority of vaccine will be in multi-dose vials, the remainder in single-dose syringes or nasal sprayers. The aim is to have enough vaccine in single-dose syringes (i.e., preservative free) for young children and pregnant women.

32. **Which ancillary supplies will be provided with vaccine?**
    CDC will provide needles, syringes, sharps containers and alcohol swabs.

33. **How will ancillary supplies be distributed?**
    Ancillary supplies will be distributed to the same "ship-to" sites as the vaccine. Plans for ensuring the distribution of these products are currently being developed.

34. **How will orders of ancillary supplies be transmitted?**
    Ancillary supply kits and sharps containers will be included in the vaccine order that is shipped from McKesson to the "ship-to" site.

35. **Can vaccine be sent to one address and ancillary supply kits to another address?**
    No, because of logistical considerations, vaccine and ancillary supply kit orders cannot be shipped to different addresses.

STATE ALLOTMENTS

36. **Can States request less than their full allocation?**
    Yes, States will not be required to accept vaccine they cannot store or administer.

37. **If a State requests less than their full allocation, will they have given up rights to the balance of their allocation?**
    States will not forfeit the remainder of their allotment if not all is ordered at one time.

38. **Can States share or exchange allocations of specific products with other States?**
    As with seasonal influenza vaccine, CDC will facilitate such exchanges.

STORAGE

39. **What is the cold chain?**

    Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency,

increasing the risk that recipients will not be protected against vaccine-preventable diseases. The system used to distribute and keep vaccines in good condition is called the cold chain.

40. **What is the size of storage volume for each product type?**
CDC will communicate the corresponding storage volume of 100 dose increments of each product type as soon as that information becomes available.

41. What are general requirements for vaccine storage?

Refrigerators without freezers, and stand-alone freezers, may be better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate external door. Additional information is available at http://www2a.cdc.gov/vaccine/ed/shtoolkit/storage_equipment.htm#Thermometers

42. Can I use a small single-door or bar-style (dormitory-style) unit to store vaccines?

Small single-door (dormitory-style or bar-style) combined refrigerator-freezer units should not be used for permanent vaccine storage. However, this type of unit may be adequate for temporarily storing **small quantities** of inactivated vaccines in the refrigerator compartment. Unused vaccine should be removed at the end of the business day and restored in the appropriate size refrigerator.

43. What is the recommended temperature to store H1N1?

Read the vaccine package insert for correct temperature requirements, most inactivated vaccines should be stored between 35° and 46°F (2°C and 8°C). The temperature should never fall below 35°F (2°C) or rise above 46°F (8°C).

44. How often should I check the temperature of the refrigerator or freezer?

The recommended method to ensure that a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day and electronically record the temperatures in the H1N1 Vaccine System. For further information, visit "Check the Internal Temperature" at

http://www2a.cdc.gov/vaccines/ed/shtoolkit/storage_euipment.htm#Thermometers

45. What type of thermometers do I use?

The CDC recommends using only certified calibrated thermometers for measuring vaccine storage unit temperatures. For further information, visit http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_equipment.htm#Thermometers

VACCINE ISSUES

46. **Will two doses of vaccine be required?**
We are currently awaiting information from the CDC and FDA regarding the number of doses necessary.

47. **What will be the recommended interval between the first and second dose, if two doses are needed?**
We are currently awaiting information from the CDC and FDA. For planning purposes, assume 21-28 days between the first and second vaccination.

48. **Will there be federal requirements to recall persons for their second dose, if a second dose is needed?**
There will be no federal requirement to send out recall notices. Providing information on second dose at the time of the first dose, as well as educating persons about who needs a second dose administered is important if it is needed.

49. **Will vaccine be adjuvanted?**
It is unlikely H1N1 vaccine will be adjuvanted. Definitive information will be available once clinical trial data are available.

50. **If vaccine is adjuvanted, how will it be formulated?**
Formulation will vary by provider. For Novartis, vaccine may be preformulated with adjuvant. For CSL, GSK and Sanofi Pasteur, mixing of vaccine and adjuvant at the site of administration will be necessary. Specific information on storage requirements and procedures for mixing vaccine and adjuvant will be provided by CDC. MedImmune vaccine will not be adjuvanted.

51. **Will the vaccine be administered under EUA (Emergency Use Authorization)?**
EUA will not be used for unadjuvanted vaccine if FDA licenses the vaccine under the current BLA (Biologics License Application) as a strain change.

52. **How much thimerosal-free vaccine will be available?**
It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women.

53. Will it be necessary for the first and second dose to be the same product?
Ideally, first and second doses would be from the same product. However, until clinical trials are completed it should be assumed that the products will be interchangeable. More information on this will follow.

54. **How many manufacturers are producing vaccine?**
Five manufacturers are producing vaccine for the U.S.: Sanofi Pasteur, Novartis, GSK, Medimmune and CSL.

ADMINISTERING VACCINE

55. Can the seasonal vaccine and the H1N1 vaccine be given at the same time?

It is anticipated that seasonal flu and H1N1 vaccines may be administered on the same day at different anatomical sites (e.g., right arm, left arm). However, we expect the seasonal vaccine to be available earlier than the H1N1 vaccine. The usual seasonal influenza viruses are still expected to cause illness this fall and winter. Individuals are encouraged to get their seasonal flu vaccine as soon as it is available.

56. **When will the decision to administer vaccine be made?**
For planning purposes, it should be assumed that vaccine will be available to administer in the fall.

57. **Will it be necessary for the first and second dose to be given by the same provider?**

No. Patients will need to bring vaccination history information to the other provider if they are using a different provider. Otherwise, all information should be accessible through the H1N1 Vaccine System.

REIMBURSEMENT

58. **Will insurance plans reimburse private providers for administration?**
CDC asked America's Health Insurance Plans (AHIP) and on behalf of its members. AHIP provided this response:
"Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

a) Health plans communicate directly with plan sponsors and members on the current ACIP recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions.

b) Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established"

59. **Will private providers be able to charge patients for vaccine administration if they are uninsured?**
Yes, providers may charge patients if they are uninsured. The administration fee cannot exceed the regional Medicare vaccine administration fee. For more information, go to the Centers for Medicare and Medicaid Services web site and see the state reimbursement rates for Medicare and Medicaid at www.cms.hhs.gov/

60. **Can persons be charged for vaccine administration in public health-organized large scale vaccination clinics?**
Per CDC, there will be no administration fee for vaccination in public-health organized large-scale vaccination clinics.

61. Is billing of third party payors/insurers permissible in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of a public health jurisdiction?
It is permissible to bill third party payors/insurers in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of a public health entity. Public health jurisdictions that do not currently have a robust billing system in place may not use CDC Public Health Emergency Response (PHER) funds to develop billing systems.

62. Is it permissible to charge patients a co-pay or any out-of-pocket charge in public health clinics or mass vaccinations sites/clinics conducted on behalf of a public health entity?
It is not permissible to charge patients in public health clinics or mass vaccination sites/clinics conducted by or on behalf of a public health entity.

63. What is the definition of a "public health clinic?"
A "public health clinic" is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and received PHER implementation funds to administer

H1N1 vaccine in any setting. For example, this may include a commercial community vaccinator (CCV) or other private provider that has a formal agreement with the public health entity.

64. Is it permissible to use PHER funds to offset the costs to private providers to vaccinate uninsured or under-insured persons?

It is permissible to use PHER funds to offset the costs to private providers to vaccinate the uninsured or under-insured population providing that the jurisdiction has systems in place to assure accountability through auditing and/or other means of accountability. Those that do not have current systems in place are encouraged not to use PHER funds to develop systems of accountability.

OTHER

What about the use of antivirals to treat 2009 H1N1 infections?

Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu by keeping flu viruses from reproducing in your body. If you get sick, antiviral drugs can make your illness milder and make you feel better faster. They may also prevent serious flu complications. This fall, antivirals may be prioritized for persons with severe illness or those at higher risk for flu complications.

Who is responsible to contact and distribute the vaccine to vaccinator-only sites?

LINCS agencies in collaboration with the Local Health Departments are responsible for sites in their respective jurisdiction.

How will information about vaccine-receiving sites be transmitted to McKesson?

The NJISS Inventory Monitoring Ordering Distribution System (IMODS) will transmit orders to CDC. These orders will be sent to McKesson the morning after they arrive at CDC. CDC is working with McKesson to determine how the vaccine and ancillary supply components of the orders will be handled and the shipment timeline, relative to vaccine orders.

Will states be able to determine where specific presentations of vaccine (multi-dose vials, single dose syringes, and nasal sprayers) are directed?

Providers will select the specific presentation of vaccine when placing their order electronically in NJISS. The NJIIS will be able to track the vaccine to know where and what vaccine has been shipped by way of a report that is generated by McKesson.